UNITED STATES DISTRICT COURT
SOUTHERN DISTICT OF NEW YORK

QUINTESSA HUEY, Individually and on behalf of All Others Similarly Situated, Plaintiff, vs. ANAVEX LIFE SCIENCES CORPORATION and CHRISTOPHER U. MISSLING, Defendants.	Case No.: 1:24-cv-01910-CM **AMENDED COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS** CLASS ACTION DEMAND FOR JURY TRIAL

Lead Plaintiff Quintessa Huey ("Plaintiff"), individually and on behalf of all other persons similarly situated, by her undersigned attorneys, alleges the following based upon personal knowledge as to herself and her own acts, and upon information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of documents filed by Anavex Life Sciences Corporation ("Anavex" or the "Company") with the United States Securities and Exchange Commission ("SEC"), wire and press releases, analyst reports and news articles, information readily obtainable on the Internet, and other available material and data.

Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities action on behalf of all persons who purchased Anavex stock on the NASDAQ between February 1, 2022 and January 1, 2024, inclusive (the "Class Period"), against Anavex and certain of its officers and/or directors for violations of the Securities Act of 1934 (the "1934 Act"). As set forth below, Defendants violated Section 10(b) of the 1934

Act by failing to disclose pertinent information relevant to the Company or, alternatively, providing information about the Company which was misleading or deceptive.

2. Anavex is a biopharmaceutical company attempting to develop treatments for central nervous system diseases. To date, Anavex has never successfully completed a clinical trial program, has never received approval from the FDA to market any of its drugs, and has never generated any revenue from the sale of its products. Yet Anavex has garnered tremendous interest among retail investors through colorful press releases, third-party promoters, and hyped-up announcements about its latest and greatest discoveries and clinical trials. Anavex has taken advantage of this retail interest over the years and raised millions of dollars in new investor money through at-the-market stock sales. This money, in turn, has kept Anavex well-capitalized and allowed its longtime CEO, Defendant Christopher U. Missling ("Missling"), to line his pockets with ludicrous multi-million dollar compensation packages. The events at issue in this lawsuit comprise just the latest instance of investor abuse at the hands of Anavex and Missling.

3. ANAVEX 2-73 is Anavex's lead drug candidate. During the Class Period, Anavex was testing the drug in various clinical trials for the treatment of Rett Syndrome. The relevant clinical trials included Anavex's U.S.-based Phase 2 trial, a Phase 3 trial referred to as the AVATAR trial, and a Phase 2/3 trial referred to as the EXCELLENCE trial. Unbeknownst to investors, the clinical data generated in these trials was insufficient to support an application for regulatory approval with the FDA. However, instead of disclosing that stark reality, Anavex and Missling repeatedly obscured the truth by mischaracterizing the results. They did this by presenting investors with data using selective "endpoint" evaluations even though these "endpoint" evaluations were not permitted by the FDA.

4. All clinical trials rely on endpoint evaluations or measurements to assess the clinical benefit of the drug being tested. The endpoints are predefined within the clinical trial's study protocol. In the field of Rett Syndrome therapeutics, the FDA requires a specific co-primary endpoint that must be used in any clinical trial for a Rett Syndrome drug: the Rett Syndrome Behavior Questionnaire ("RSBQ") anchored with the Clinical Global Impression Scale–Improvement ("CGI-I"). The FDA determined this requirement in October 2017 in connection with a Rett Syndrome drug named DAYBUE.

5. At all relevant times during the Class Period, Missling knew that the FDA required RSBQ with CGI-I as a co-primary endpoint. Yet despite this knowledge, Missling consistently and repeatedly told analysts and investors that Anavex would use a variation of these endpoints in its clinical trials. He referred to this variation as the Rett Syndrome Behavior Questionnaire – Area Under the Curve ("RSBQ AUC"). By making these representations, Missling created the false impression that Anavex would in fact use this endpoint in its trials and that the FDA had authorized Defendants to do so, which was not the case.

6. There is a significant and material difference between the FDA-approved RSBQ and CGI-I endpoints on the one hand and Anavex's RSBQ AUC endpoint on the other hand. The former measures a patient's improvement by comparing their health at the beginning of treatment and their health at the end of treatment; the latter takes readings throughout the course of treatment thereby allowing multiple readings to influence the final result. Put differently, RSBQ AUC could allow Anavex to claim success even though a patient was just as sick at the end of treatment than she was at the beginning of treatment.

7. That is precisely what Anavex and Missling did. Knowing the benefits of its RSBQ AUC endpoint, they used it to their advantage to provide investors and analysts with a misleading

impressions of the clinical data they obtained from their trials. The truth concerning ANAVEX 2-73 and its ability to treat Rett Syndrome did not emerge until the end of the Class Period when Defendants finally admitted to the public that the drug did not demonstrate a clinical benefit under the FDA-approved co-primary endpoints, *i.e.*, RSBQ and CGI-I.

8. Defendants' deception gave investors false hope that ANAVEX 2-73 had the clinical data behind it to secure regulatory approval on the timetable they claimed. Consequently, Defendants' false statements about ANAVEX 2-73 misled investors and analysts in terms of valuing Anavex and its prospects for commercializing a Rett Syndrome treatment. For investors who bought in on the hype around Anavex's supposed clinical trial success, they suffered significant damages when the truth finally revealed itself. Defendants should be held accountable.

II. JURISDICTION AND VENUE

9. Jurisdiction is conferred by Section 27 of the 1934 Act, 15 U.S.C. §78aa. The claims asserted herein arise under Sections 10(b) and 20(a) of the 1934 Act, 15 U.S.C. §§78j(b) and 78t(a), and SEC Rule 10b-5, 17 C.F.R. §240.10b-5.

10. Venue is proper in this District pursuant to Section 27 of the 1934 Act. The violations of law complained of herein occurred in part in this District, including the dissemination of materially false and misleading statements herein into this District.

11. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

12. Lead Plaintiff Quintessa Huey purchased Anavex stock as described in the Certification filed previously in connection with her motion for lead plaintiff and incorporated by reference. Dkt. No. 15-1. Plaintiff suffered damages in connection with her purchase of Anavex stock.

13. Anavex is incorporated in Delaware. Anavex's headquarters is 630 5th Avenue, 20th Floor, New York, New York, 10111. Shares of the Company's stock trade on the NASDAQ under the ticker symbol "AVXL."

14. Missling is and was at all material times Board Chair, CEO, President, and Secretary of Anavaex.

15. Missling (the "Individual Defendant"), because of his position with the Company, possessed the power and authority to control the content's of Anavex's quarterly reports, press releases, and presentations to securities analysts, money and portfolio managers, and investors, *i.e.*, the market. He was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of his position with the Company and his access to material information available to him but not the public, the Individual Defendant knew that adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were then materially false and misleading. The Individual Defendant is liable for the false statements pleaded herein.

IV. SUBSTANTIVE ALLEGATIONS

Corporate Background

16. Originally named Thrifty Printing Inc., Anavex began as a provider of online photofinishing services. Then, in early 2007, Anavex announced that it would be changing its name (to Anavex) and reemerging as a biopharmaceutical company. The press release announcing the change stated, in pertinent part, as follows: "We have changed our name to reflect the new direction of the Company which is intended to be development of medicinal drugs under a letter of intent announced December 28, 2006. Under the letter of intent, the [C]ompany is to acquire a portfolio of innovative drug compounds."

17. Anavex has generated nothing in terms of revenue since entering the biopharmaceutical industry. Its lead drug candidate is ANAVEX 2-73 which, according to Anavex, is being developed to treat Alzheimer's disease, Parkinson's disease, and other central nervous system diseases, including Rett Syndrome. Despite years of testing, Anavex has not completed successfully a clinical trial program for ANAVEX 2-73 and, consequently, has not submitted an NDA for ANAVEX 2-73 to the FDA. Without marketing approval from the FDA, Anavex has accumulated a deficit of approximately $200 million (as of September 30, 2021).

18. To fund operations, Anavex has traditionally relied on selling stock to retail investors through stock purchase agreements with Lincoln Park Capital. The agreements gave Anavex the right to sell to Lincoln Park Capital various amounts of stock. After purchasing the shares, Lincoln Park Capital would then resell them to retail investors in the market. Anavex entered into several of these agreements since 2013, including: a) July 2013 for $10 million; b) October 2015 for $50 million; c) June 2019 for $50 million; and d) February 2023 for $150 million.

Anavex has also conducted at-the-market offerings, including a July 2018 offering for $50 million and May 2020 offering for $50 million.

19. Anavex's ability to raise money through these equity offerings depended on maintaining an elevated stock price as well as creating demand for the stock in the market. To do this, Anavex historically relied on third-party "consultants" to promote its stock. For example, in 2013, Anavex paid $128,575 for investor relations, an increase of almost 20% from the prior fiscal year. For fiscal 2014, Anavex's total operating expenses increased to $2.9 million, which was "mainly attributable" to "an increase in investor relations expenses." In prior years, Anavex engaged an entity named Primoris to "implement a communications program to support Anavex's corporate growth strategy." Primoris' other clients at the time consisted of penny stock companies. Regulatory agencies, including the British Columbia Securities Commission in 2013 and the SEC in 2015, have investigated Anavex for its promotional tactics.

20. Despite having never generated any revenue, Defendant Missling has received exorbitant compensation. Missling's total compensation for 2021 was approximately $9.4 million; $6.7 million for 2022; and $3.8 million for 2023.

21. Missling's compensation consisted of a base salary, cash bonus, and equity compensation awards, all of which increased based upon Missling's ability to publicize and advance Anavex's drugs into clinical trials. For example, in April 2022, Missling's annual salary increased from $550,000 to $700,000 based in part on Anavex's advances in clinical trials. Likewise, in June 2022, Missling received options worth approximately $6 million that would vest upon hitting performance milestones, including the topline data readout for the EXCELLENCE trial and publication of the AVATAR trial data. Missling's annual compensation was approximately 10x that of Anavex's median employee.

The U.S.-Based Phase 2 Trial

22. Anavex's lead drug candidate has always been ANAVEX 2-73. The drug was initially introduced to investors as a treatment for Alzheimer's Disease and then, over the years, expanded as a possible treatment for other neurological disorders such as Parkinson's Disease. The possibility of using ANAVEX 2-73 as a treatment for Rett Syndrome first appeared on investor's radars when Anavex reported "positive preclinical data" in February 2016. Shortly thereafter, in May 2016, Anavex secured Orphan Drug Designation for ANAVEX 2-73 in Rett Syndrome.

23. In 2017, Anavex announced its receipt of a financial grant from the International Rett Syndrome Foundation to cover clinical trial costs for a U.S. multicenter Phase 2 clinical trial of ANAVEX 2-73 for the treatment of Rett Syndrome. The Phase 2 trial was scheduled to begin upon the FDA's approval of the Company's investigational new drug (IND) application.

24. Anavex received approval for the Phase 2 trial in October 2018 and commenced the study several months later in March 2019. The trial was a randomized double-blind, placebo-controlled safety, tolerability, pharmacokinetic and efficacy study. Pharmacokinetic and dose findings were investigated in a total of 25 patients over a 7-week treatment period. Primary and secondary endpoints include safety as well as Rett syndrome conditions such as cognitive impairment, motor impairment, behavioral symptoms and seizure activity.

25. Analysts applauded Anavex's decision to expand ANAVEX 2-73 to Rett Syndrome. For example, Roth Capital Partners wrote in January 2019 that the Rett Syndrome program and, in particular, the Phase 2 study was "high risk and high reward" given its "orphan population with no approved therapy or standard of care." This, in turn, could support an "accelerated approval" and "premium orphan pricing."

The AVATAR Trial

26. In June 2019, with its U.S.-based Phase 2 trial underway, Anavex commenced its AVATAR trial. Anavex's AVATAR trial was initially registered as a Phase 2 trial to evaluate the safety and efficacy of ANAVEX 2-73 in approximately 33 patients with Rett Syndrome over a 7-week treatment period.

27. Anavex posted its trial protocol for the AVATAR trial on ClinicalTrials.gov. ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The website launched in 2000 and was created as part of the Food and Drug Administration Modernization Act of 1997. This law required the U.S. National Institutes of Health (NIH) to create a database of clinical trials that have an investigational new drug (IND) application to test investigational drugs for serious or life-threatening diseases. Since then, ClinicalTrials.gov has expanded based on other laws, regulations, and policies (including the FDA Amendments Act of 2007) and requires sponsors and investigators to submit research studies and more information about these studies, including in particular the submission of full trial protocols and statistical analysis plans. These laws, regulations, and policies require sponsors to provide the public with the necessary information about ongoing and completed studies.

28. According to Anavex's submission of the AVATAR trial protocol on ClinicalTrials.gov dated May 6, 2019, Anavex intended to use the following endpoints for the AVATAR trial:

Primary Outcome Measures	1. Incidence of Adverse Events Incidence of Adverse Events [Time Frame: 7 weeks] 2. Maximum Plasma Concentration [Cmax] of ANAVEX2-73 PK of ANAVEX2-73 and metabolite [Time Frame: 7 weeks]

	3. Area Under the Curve [AUC] of ANAVEX2-73 PK of ANAVEX2-73 and metabolite [Time Frame: 7 weeks] 4. Lipid panel Significant laboratory findings [Time Frame: 7 weeks]
Secondary Outcome Measures	1. RSBQ Change from baseline to End of Treatment (EOT) in the Rett Syndrome Behaviour Questionnaire (RSBQ) [Time Frame: 7 weeks] 2. CGI-I Change from baseline to End of Treatment (EOT) in the Clinical Global Impression Improvement Scale (CGI-I) score [Time Frame: 7 weeks]

29. Analysts reported favorably on the start of the AVATAR trial. In particular, Roth Capital Partners wrote in July 2019 that the combination of the U.S.-based "Phase 2 study topline data emerging in YE19 and into early-2020" followed by the AVATAR study data "could provide a commercial path for ANAVEX 2-73 as the first-to-market for the treatment of Rett [S]yndrome in US and Europe."

The EXCELLENCE Trial

30. Anavex commenced a third trial shortly after the start of the AVATAR study. On September 4, 2019, while the U.S.-based Phase 2 trial and AVATAR trial were both underway, Anavex started the EXCELLENCE trial to test ANAVEX 2-73 in Rett Syndrome. The trial was a Phase 2/3 study in pediatric patients with Rett Syndrome designed to evaluate the safety and efficacy of ANAVEX 2-73 in at least 69 pediatric patients, aged 5 to 18, over a 12-week treatment period.

31. According to Anavex's submission of the EXCELLENCE trial protocol on ClinicalTrials.gov dated March 8, 2020, Anavex intended to use the following endpoints for the EXCELLENCE trial:

Primary Outcome Measures	1. RSBQ Change from baseline to End of Treatment (EOT) in the Rett Syndrome Behaviour Questionnaire (RSBQ) [Time Frame: 12 weeks] 2. CGI-I Change from baseline to End of Treatment (EOT) in the Clinical Global Impression Improvement Scale (CGI-I) score [Time Frame: 12 weeks]
Secondary Outcome Measures	1. Anxiety, Depression, and Mood Scale (ADAMS) Anxiety, Depression, and Mood Scale (ADAMS) [Time Frame: 12 weeks] 2. Motor Behavioral Assessment-7 dynamic pediatric items (MBA-Ped7) Motor Behavioral Assessment-7 dynamic pediatric items (MBA-Ped7) [Time Frame: 12 weeks] 3. Children's Sleep Habits Questionnaire (CSHQ) Children's Sleep Habits Questionnaire (CSHQ) [Time Frame: 12 weeks] 4. Seizure Frequency via seizure diary Seizure Frequency via seizure diary [Time Frame: 12 weeks] 5. Incidence of Adverse Events Incidence of Adverse Events [Time Frame: 12 weeks]

32. Importantly, the EXCELLENCE study's trial protocol identified RSBQ with CGI-I as the study's co-primary endpoints instead of the RSBQ AUC measure that Anavex would ultimately end up using when reporting topline results for the AVATAR trial. The study protocol identified RSBQ and CGI-I as the trial's co-primary endpoints because failure to do so would have

disqualified it from serving as a pivotal study in support of any future NDA for ANAVEX 2-73 to treat Rett Syndrome, given the FDA's requirement to use RSBQ with CGI-I as co-primary endpoints in Rett Syndrome clinical trials.

33. Analysts reported favorably on the EXCELLENCE trial. For example, Cantor Fitzgerald wrote in August 2020 that the EXCELLENCE trial presented a "possibility that a more robust signal may be observed" in the study and that "positive results from these studies may be sufficient to file an NDA for [Rett Syndrome] . . . ."

The LAVENDER Trial

34. Anavex was not alone in its efforts to develop a treatment for Rett Syndrome. Neuren Pharmaceuticals, Ltd., started developing DAYBUE (named trofinetide at the time) in 2012. Neuren Pharmaceuticals conducted two Phase 2 trials for DAYBUE with the last one completing in 2016. By this point, DAYBUE had already been granted FDA Fast Track Status and Orphan Drug Designation in the U.S. and Europe for the treatment of Rett Syndrome. Though neither company mentioned the other in its SEC filings, both Anavex and Acadia Pharmaceuticals were attempting to be the first to obtain FDA approval for a Rett Syndrome treatment.

35. On October 12, 2017, Neuren Pharmaceuticals held its end-of-phase 2 meeting with the FDA. End-of-phase 2 meetings are standard, required meetings where the FDA will consider, comment, revise and/or approve plans for further clinical trials, *i.e.*, pivotal Phase 3 trials intended to be used for New Drug Applications in the future. The purpose of an end-of-phase 2 meeting is to determine the pathway for proceeding to a Phase 3 study, to evaluate the Phase 3 plan and protocol for adequacy, to assess pediatric safety and effectiveness, and to identify any additional information that would be needed to support a marketing application. This provides the sponsor (drug company) an opportunity to get FDA input prior to conducting the Phase 3 study.

36. At the end-of-phase 2 meeting, Neuren Pharmaceuticals proposed a subsequent Phase 3 study that would be a double-blind, placebo-controlled, parallel-group study design. The FDA advised that there were multiple concerns with the RSBQ as a primary endpoint. At the encouragement of the FDA, Neuren Pharmaceuticals agreed to study the Clinical Global Impression-Improvement (CGI-I) scale as an anchoring functional measure as a co-primary endpoint with the Rett syndrome Behavior Questionnaire (RSBQ). Thus, the CGI-I was directly recommended and approved by the FDA as an anchoring measure of function to be used as a co-primary endpoint.

37. In 2018, Neuren Pharmaceuticals licensed DAYBUE to Acadia Pharmaceuticals instead of proceeding with the Phase 3 study itself. The license agreement granted Acadia Pharmaceuticals an exclusive North American license to develop and commercialize DAYBUE for Rett Syndrome.

38. In October 2019, Acadia Pharmaceuticals commenced its Phase 3 LAVENDER study. The study was a randomized, double-blind placebo-controlled study evaluating DAYBUE (trofinetide) in approximately 180 girls and young women 5 to 20 years of age with Rett Syndrome. Half of study participants were to receive DAYBUE and the other half to receive placebo. Co-primary efficacy endpoints of the study were set to measure symptom improvement using the Rett Syndrome Behavior Questionnaire (RSBQ), a caregiver assessment, and the Clinical Global Impression Scale-Improvement (CGI-I), a clinician assessment, as required by the FDA pursuant to its direction at the end-of-phase 2 meeting in October 2017. Acadia Pharmaceuticals expected results from the LAVENDER trial in 2021.

Trial Results

The U.S.-Based Phase 2 Trial

39. Anavex's U.S.-based Phase 2 trial was the first to finish. On December 15, 2020, Anavex issued a press release announcing top-line results from the trial. In pertinent part, the top-line results from the press release were as follows:

> The primary endpoint of the trial was safety. The convenient oral liquid once-daily dosing of 5 mg ANAVEX®2-73 was well-tolerated and demonstrated dose-proportional PK (pharmacokinetics). Adverse events related to study drug were similar between ANAVEX®2-73 (13.3%) and placebo (10%), with no reported serious adverse events (SAEs). The safety profile of ANAVEX®2-73 in this trial is consistent with prior clinical trial data.
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> All secondary efficacy endpoints of the trial showed statistically significant and clinically meaningful sustained improvements for ANAVEX®2-73 compared to placebo, consisting of the Rett Syndrome Behaviour Questionnaire (RSBQ) ($p = 0.048$) and the Clinical Global Impression Improvement Scale (CGI-I) score ($p = 0.014$) in the intent-to-treat (ITT) population ($n = 25$). Statistically significant differences in patient symptoms between the active and placebo groups occurred as early as 4 weeks following the initiation of ANAVEX®2-73 administration. Improvements in RSBQ Total scores were correlated with parallel decreases (improvements) in glutamate plasma levels.
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> "The outcome of this trial is very promising in terms of both safety and clinical improvement. Despite the challenges of the older age of the cohort (patients were over 18 years of age) and the relatively low dose (5 mg daily), ANAVEX®2-73 demonstrated clinically meaningful improvements in outcome measures evaluating multiple impairments," commented Walter E Kaufmann, MD, Principal Investigator. Subsequent to his appointment as Principal Investigator of this Phase 2 ANAVEX®2-73 trial in adult Rett syndrome patients, Dr. Kaufmann joined Anavex as Chief Medical Officer. He also said, "Moreover, the convergent clinical evidence was supported by parallel changes in a key biomarker of disease. This strong body of data opens the possibility of successful treatment for both adults and children with Rett syndrome and early interventions for modifying the course of the disease."
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> Based on the results in this first of its kind U.S. Phase 2 (ANAVEX®2-73-RS-001) study in adult patients with Rett syndrome, Anavex is planning to meet with FDA to discuss the approval pathway. There are no FDA-approved drugs for Rett syndrome. ANAVEX®2-73 has Fast Track designation, Rare Pediatric Disease

designation and Orphan Drug designation from the FDA for the treatment of Rett syndrome and may be considered for accelerated approval.

The LAVENDER Trial

40. Acadia Pharmaceuticals completed its Phase 3 LAVENDER trial for DAYBUE the following year. On December 6, 2021, Acadia Pharmaceuticals issued a press release announcing top-line results from the trial. In pertinent part, the top-line results from the press release were as follows:

> Acadia Pharmaceuticals Inc. (Nasdaq: ACAD) today announced positive top-line results from the pivotal, Phase 3 Lavender™ study evaluating the efficacy and safety of [DAYBUE] in 187 girls and young women aged 5-20 years with Rett syndrome. The 12-week placebo-controlled study demonstrated a statistically significant improvement over placebo for both co-primary endpoints. On the Rett Syndrome Behaviour Questionnaire (RSBQ), change from baseline to week 12 was -5.1 vs. -1.7 (p=0.0175; effect size=0.37). The Clinical Global Impression–Improvement (CGI-I) score at week 12 was 3.5 vs. 3.8 (p=0.0030; effect size=0.47). The RSBQ is a caregiver assessment of the core symptoms of Rett syndrome and the CGI-I is a global physician assessment of worsening or improving of Rett syndrome.
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> Additionally, [DAYBUE] demonstrated a statistically significant separation over placebo on the key secondary endpoint, the Communication and Symbolic Behavior Scales Developmental Profile™ Infant-Toddler Checklist–Social composite score (CSBS-DP-IT–Social) change from baseline to week 12 was -0.1 vs. -1.1 (p=0.0064; effect size=0.43).
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> "These are encouraging results for patients and families affected by Rett syndrome. Patients reported improvements in core symptoms, like being able to respond to a choice when asked by their parents, or experiencing more freedom from the repetitive hand movements that create obstacles in other areas of their lives," said Jeffrey L. Neul, M.D., Ph.D., Annette Schaffer Eskind Chair and Director, Vanderbilt Kennedy Center; Professor of Pediatrics, Division of Neurology, Pharmacology, and Special Education, Vanderbilt University Medical Center and Lavender study investigator. "The positive Lavender study results support a potential treatment for Rett syndrome and represent an important step forward in addressing this rare and serious neurological disease."

41. The LAVENDER study results did, in fact, support a potential treatment for Rett Syndrome. On July 18, 2022, Acadia Pharmaceuticals submitted an NDA for DAYBUE. On March

10, 2023, the FDA approved the NDA and DAYBUE for treatment against Rett Syndrome. Importantly, the FDA's approval was premised upon the LAVENDER study and its primary endpoint data consisting of RSBQ and CGI-I, which had been required by the FDA during the end-of-phase 2 meeting back in October 2017.

The AVATAR Trial

42. The next trial to finish was Anavex's AVATAR trial in February 2022. Anavex's disclosure of the trial data created significant fallout due to what many analysts and investors regarded as a last-minute change to the study protocol in an attempt to put a positive spin on the trial data and conceal potentially negative results.

43. The AVATAR study commenced in June 2019 and completed in February 2022. Throughout the study, Anavex updated the trial protocol multiple times on ClinicalTrials.gov but kept the primary and secondary endpoints the same until the very end of the trial.

44. Likewise, despite hosting a total of 14 quarterly calls, special calls, and inventor conference presentations, Anavex never disclosed an intent to change the endpoints. For example, during an earnings conference call on November 24, 2021, Missling stated in pertinent part that:

> Starting with our lead drug candidate 2-73. We expect topline results from the second placebo-controlled AVATAR study for the treatment of our patients with Rett syndrome, which are expected to be announced around calendar year end 2021. This study took place in Australia and the United Kingdom using a higher dose than the U.S.-based Phase II study and enrolled 33 patients over a 7-week treatment period, including ANAVEX 2-73-specific precision medicine biomarkers.
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> . . .
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> <Pete George Stavropoulos, Cantor Fitzgerald & Co., Research Division – Biotech Analyst>: Very helpful. We also saw that you made a few changes to the primary and secondary endpoints in the EXCELLENCE study. Can you give us a -- help us understand what drove those decisions? Was it a result of advice or interactions with the FDA or any other regulatory agency?

> <Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: Right. So we have noticed that the RSBQ is really the most -- more rigorous endpoint. It is really going through 45 very dedicated questions and detailed questions, which can be answered very precisely. There's also the ability, which we have seen and we have demonstrated that in our presentation of doing sub-analysis of the sub-scores of the entire score of the RSBQ score. However, when we looked at the CGI-I, we noticed that there was a weaker ability to make this because it's really a global assessment. And it also has a very known and it's published weak, I would say, reliability. But we basically are including that still, but we didn't want to overemphasize that score. So that was the background for the focus on the RSBQ.

45. Despite direct questioning on changing endpoints, and although AVATAR was on the verge of concluding with topline results to be delivered within weeks of this late November announcement, Missling did not announce changes to the study design or endpoints during this call, *i.e.*, the November 24, 2021 earnings conference call.

46. On January 15, 2022, the Company updated the AVATAR study design for the tenth time. The update did not change the endpoint measures.

47. Then, finally on January 18, 2022, Anavex updated the AVATAR study design and, importantly, revised the endpoint measures. The AVATAR trial's primary and secondary endpoint measures were revised as follows:

Primary Outcome Measures	1. RSBQ Drug exposure-dependent response of the Rett Syndrome Behaviour Questionnaire (RSBQ) Total score [Time Frame: 7 weeks] 2. Incidence of Adverse Events Incidence of Adverse Events [Time Frame: 7 weeks]
Secondary Outcome Measures	1. CGI-I Drug exposure-dependent response of the Clinical Global Impression of Improvement Scale (CGI-I) score [Time Frame: 7 weeks]

	2. Anxiety, Depression, and Mood Scale (ADAMS) Drug exposure-dependent response of the Anxiety, Depression, and Mood Scale (ADAMS) [Time Frame: 7 weeks] 3. Maximum Plasma Concentration [Cmax] of ANAVEX2-73 PK of ANAVEX2-73 and metabolite [Time Frame: 7 weeks] 4. Area Under the Curve [AUC] of ANAVEX2-73 PK of ANAVEX2-73 and metabolite [Time Frame: 7 weeks]

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48. For ease of reference, the following table taken from ClinicalTrials.gov illustrates the revisions to the endpoints:

Primary Outcome Measures	1. Incidence of Adverse Events Incidence of Adverse Events [Time Frame: 7 weeks] 2. ~~Maximum Plasma Concentration [Cmax] of ANAVEX2-73~~ ~~PK of ANAVEX2-73 and metabolite~~ ~~[Time Frame: 7 weeks]~~ 3. ~~Area Under the Curve [AUC] of ANAVEX2-73~~ ~~PK of ANAVEX2-73 and metabolite~~ ~~[Time Frame: 7 weeks]~~ 4. ~~Lipid panel~~ ~~Significant laboratory findings~~ ~~[Time Frame: 7 weeks]~~	1. RSBQ Drug exposure-dependent response of the Rett Syndrome Behaviour Questionnaire (RSBQ) Total score [Time Frame: 7 weeks] 2. Incidence of Adverse Events Incidence of Adverse Events [Time Frame: 7 weeks]
Secondary Outcome Measures	1. ~~RSBQ~~ ~~Change from baseline to End of Treatment (EOT) in the Rett Syndrome Behaviour Questionnaire (RSBQ)~~ [Time Frame: 7 weeks] 2. ~~CGI-I~~ ~~Change from baseline to End~~ of ~~Treatment (EOT) in~~ the ~~Clinical Global Impression Improvement~~ Scale (~~CGI-I) score~~ [Time Frame: 7 weeks]	1. CGI-I Drug exposure-dependent response of the Clinical Global Impression of Improvement Scale (CGI-I) score [Time Frame: 7 weeks] 2. Anxiety, Depression, and Mood Scale (ADAMS) Drug exposure-dependent response of the Anxiety, Depression, and Mood Scale (ADAMS) [Time Frame: 7 weeks] 3. Maximum Plasma Concentration [Cmax] of ANAVEX2-73 PK of ANAVEX2-73 and metabolite [Time Frame: 7 weeks] 4. Area Under the Curve [AUC] of ANAVEX2-73 PK of ANAVEX2-73 and metabolite [Time Frame: 7 weeks]

49. Anavex also "upgraded" the AVATAR trial from a Phase 2 trial to a Phase 3 trial, suggesting it could be used as a "pivotal" study to support an NDA for ANAVEX 2-73. This left investors with the impression that Anavex's progress towards achieving regulatory approval was potentially in line with or relatively equal to Acadia Pharmaceuticals who had just recently completed the LAVENDER trial for DAYBUE's NDA.

50. The Company issued no press release nor issued any comment on the change in primary design, despite having participated in the J.P. Morgan Annual Health Conference just days before, on January 13, 2022.

51. Consequently, when Anavex reported top-line results from the AVATAR trial on February 1, 2022, it reported endpoint data that was largely unexpected by analysts and investors. In pertinent part, Anavex reported the following top-line results for the AVATAR:

> Anavex Life Sciences Corp. ("Anavex" or the "Company") (Nasdaq: AVXL), a clinical-stage biopharmaceutical company developing differentiated therapeutics for the treatment of neurodegenerative and neurodevelopmental disorders including Alzheimer's disease, Parkinson's disease, Rett syndrome and other central nervous system (CNS) disorders, today reported positive top-line results from the Phase 3 randomized, double-blind, placebo-controlled AVATAR trial of ANAVEX®2-73 (blarcamesine) in adult female patients with Rett syndrome and demonstrated a statistically significant improvement over placebo for the primary efficacy endpoint as well as for all the secondary efficacy endpoints. Convenient once daily oral liquid doses of up to 30mg ANAVEX®2-73 were well tolerated with very good medication compliance. Rett syndrome is a chronic CNS disease caused by a spontaneous mutation of one gene, MECP2.
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> . . .
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> In the primary endpoint, RSBQ AUC, ANAVEX®2-73 induced a statistically significant and clinical meaningful improvement in 72.2% of patients as compared to 38.5% on placebo; ($p = 0.037$) with a Cohen's d effect size of 1.91 (very large). The secondary efficacy endpoints also demonstrated statistically significant and clinical meaningful improvements. For the ADAMS, a measure of emotional behavior symptoms, a significantly higher proportion of ANAVEX®2-73 treated adult patients with Rett syndrome (52.9%) than placebo-treated patients (8.3%) showed improvement ($p = 0.010$), which corresponded to a Cohen's d effect size of 0.609 (large). For the CGI-I, more patients achieved clinically meaningful CGI-I response over the treatment duration in the ANAVEX®2-73-treated group (72.2%) than in the placebo group (38.5%); ($p = 0.037$) with a Cohen's d effect size of 1.91 (very large).

52. Analysts expressed confusion about the AVATAR outcomes, analyses, and results. For instance, on February 1, 2022, Yun Zhong of BTIG called out the "surprising primary endpoint

change" and questioned "what is the true clinical benefit from ANAVEX 2-73 treatment." Zhong further wrote, "[t]here could have been less investor confusion if Anavex had chosen to report the RSBQ total score from the AVATAR study as well [as RBSQ AUC]."

53. Also on February 1, 2022, Charles Duncan of Cantor Fitzgerald wrote "AVATAR P3 Read Makes Us Wonder About Clinical Endpoints in RETT," and lowered the target on Anavex shares from $27 to $16. In pertinent part, he wrote:

> Although the primary endpoint of drug exposure-dependent response Rett Syndrome Behavior Questionnaire (RSBQ) AUC meets statistical significance (p=0.037), we cannot say clinical proof-of-concept has been established until there is greater disclosure of the data which demonstrates it using well-defined approvable endpoints to underscore clinical utility.
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> Given these observations, and challenges in interpreting some of the efficacy endpoints, we note inconsistency with our prior diligence with KOLs on RSBQ, which is what we had thought was the primary endpoint, as given on clinicaltrials.gov. Therefore, we now believe it is prudent to project that this P3 may need to be supported with additional clearly positive clinical data to support an NDA submission, including possibly conducting an additional P3.
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> . . .
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> Another interesting detail is that Anavex anchored its RSBQ response to the CGI-I response, as a result of communication it had with the FDA in which it was relayed that the Agency wanted to see clinical outcome impressions linked to RSBQ scores. Although this 'concept' makes sense to us, as clinical meaningfulness is a key consideration for efficacy and thus pharmaco-economic value, in our view, the conclusion and timing is odd to us given our past KOL diligence indicating that RSBQ is a sufficient pivotal endpoint, and we find the company's execution even more confounding. Rather than redefine the primary endpoint following the conduct of the trial (albeit perhaps in advance of unblinding), we would have preferred to see greater transparency on RSBQ and CGI-I scores, along with a regression analysis showing their correlation.

54. Other market analysts explicitly called out Anavex for manipulating AVATAR's endpoints and misleading investors. Adam Feuerstein, a senior biotech columnist for *STAT News*, told readers that by changing the endpoints on January 18, 2022, Anavex was "allow[ed] to claim

success when the drug most likely failed." According to Feuerstein, Anavex switched its endpoints for the study to a "meaningless RSBQ and CGI 'responder' analysis, rather than disclosing numerical changes in the scales over time," thereby allowing the Company to "claim[] success based on 72% of patients showing 'improvement' on RSBQ scale vs 38% on placebo." Feuerstein contrasted Anavex's data readout with Acadia Pharmaceuticals' readout for the LAVENDER study, which used RSBQ and CGI-I.

55. The manner in which Anavex used RSBQ and CGI-I in the AVATAR trial was nonconventional and inappropriate relative to industry practices and academic standards. RSBQ is a questionnaire assessment administered to a Rett Syndrome patient by her caregiver. Efficacy is measured by comparing the patient's baseline score with her score at the end of the study. To confirm the reliability of the RSBQ measure, the assessment is anchored with CGI-I. CGI-I is a similar assessment but completed by the patient's clinician to assess how much the patient's illness has improved or worsened relative to a baseline state at the beginning of the intervention. Importantly, both measures (RSBQ and CGI-I) compare final end-of-treatment scores against baseline scores to determine efficacy. These are the FDA-approved endpoints for Rett Syndrome clinical trials.

56. Anavex did not adhere to these FDA-approved endpoints for AVATAR. Instead, it created a variation of the RSBQ endpoint by taking into account the patient's "response" to ANAVEX 2-73 during the course of the trial itself. Put differently, the accepted outcome, RSBQ, compares a patient's status at the end of the trial to their status at the start of the trial, while Anavex's alternative measurement, which it described as "RSBQ Area Under the Curve" or "RSBQ AUC", was a sum of patient RSBQ scores *during* the trial. Consequently, so long as the patient exhibited improvement at some point during the course of the trial, Anavex's RSBQ AUC

endpoint would potentially show positive results even if the last measurement was the same as or worse than the initial reading. Anavex claimed that this RSBQ AUC analysis represented "a summary measure that combine[d] both treatment effect and disease progression into one composite score." Anavex provided no evidence that its "RSBQ AUC" approach was validated or embraced by other researchers or the FDA.

57. There is a material difference between RSBQ AUC on the one and RSBQ anchored with CGI-I on the other hand, as explained above and confirmed by key opinion leaders in the Rett Syndrome field. A "key opinion leader" refers to someone who is regarded as an expert and influencer among academic and industry participants. Dr. Daniel Tarquinio is the founder of the Center for Rare Neurological Diseases and a Rett Syndrome expert who has been actively involved in the development of efficacy endpoints and biomarker research to improve outcome measures clinical studies. Dr. Tarquinio is regarded as key opinion leader by analysts. According to Dr. Tarquinio, Anavex's proposed RSBQ AUC measurement was "an interesting strategy" but "a little artificial" and had not been sufficiently tested to qualify as an acceptable primary endpoint.

58. The FDA did not accept RSBQ AUC as an endpoint for pivotal Rett Syndrome clinical trials (*i.e.*, any clinical trial intended to support an NDA); in fact, the FDA required RSBQ and CGI-I to be used as co-primary endpoints for any pivotal Rett Syndrome clinical trial. Anavex knew the FDA's endpoint requirements. Indeed, the FDA instructed Anavex to use these endpoints when discussing and/or approving: Anavex's clinical trial plans and Investigational New Drug applications, or INDs, for the U.S.-based Phase 2, AVATAR, and EXCELLENCE trials prior to their commencement in March, June, and September 2019, respectively; ANAVEX 2-73's Rare Pediatric Disease designation for the treatment of Rett Syndrome in November 2019; Anavex's

application for Fast Track status in February 2020; and subsequently thereafter when providing Anavex with input on its clinical trial designs and regulatory approval packages in February 2023.

59. To be sure, Anavex met with the FDA to discuss its development program for ANAVEX 2-73 for Rett Syndrome between December 2017 and February 2018. Anavex discussed its proposed study designs for the development of ANAVEX 2-73 during the meeting. In response, the FDA provided feedback about the study design, including the primary endpoints that would be required to permit an evaluation of ANAVEX 2-73's effectiveness and safety. The FDA's feedback with respect to the trial design and endpoints is a required component of the pre-IND meeting. *See* 21 CFR 312.22. Consequently, given that the FDA had already determined that Rett Syndrome clinical trials needed to use RSBQ and CGI-I as co-primary endpoints, as stated by the FDA during DAYBUE's end-of-phase 2 meeting in October 2017, Anavex knew by February 2018 at the latest that any potential pivotal clinical trial would need to incorporate these endpoints. Anavex received notice of this requirement at various times thereafter in light of ANAVEX 2-73's Fast Track designation, which required Anavex to "receive more intensive guidance on an efficient drug development program with increased interactions and communications with FDA, including meetings." *See Best Practices for Communication Between IND Sponsors and FDA During Drug Development*, FDA GUIDANCE (Dec. 2017) (citing CDER MAPP 6025.6 & CBER SOPP 8212). Anavex's identification of the RSBQ and CGI-I co-primary endpoints in the EXCELLENCE trial's study protocol confirms its awareness of the FDA's position and understanding that it needed to adhere to that position if it wanted the trial to support a future NDA for ANAVEX 2-73.

60. Feuerstein and other analysts immediately recognized the impropriety of Anavex's RSBQ AUC measure and, in turn, doubted the significance and reliability of AVATAR's supposed

"positive" results. As a result, Anavex's stock price fell from $13.08 per share on January 31, 2022 to $11.04 per share on February 1, 2022.

61. Defendant Missling responded to the criticism Anavex was receiving from analysts. In an interview with *Investor's Business Daily*, Missling claimed that the changes to the AVATAR study had been made in December 2021 but not updated on ClinicalTrials.gov until January 18, 2022. Even if Missling changed the trial in December 2021, the changes were still made approximately three and a half months *after* Anavex completed testing in the AVATAR trial on September 30, 2021. Consequently, after the last participant in AVATAR was examined to collect final data for the primary and secondary outcome measures on September 30, 2021, Anavex changed the endpoints in December 2021 (according to Missling) or January 2022 (according to ClinicalTrials.gov), and then reported "positive" results in February 2022 when announcing completion of the trial. As *Investor's Business Daily* pointed out, the timeline of events created the impression of a company changing the goals when the drug was actually underperforming the trial's pre-specified measures.

The EXCELLENCE Trial

62. Anavex completed enrollment for the EXCELLENCE trial in February 2023 and dosing in June 2023. Drug companies typically announce topline results between six and eight weeks after study completion. Anavex, however, did not report results until January 2, 2024.

63. On January 2, 2024, Anavex issued a press release titled, "Anavex Announces Topline Results from Phase 2/3 EXCELLENCE Clinical Study in Pediatric Rett Syndrome." In pertinent part, the press release stated:

> Anavex Life Sciences Corp. ("Anavex" or the "Company") (Nasdaq: AVXL), a clinical-stage biopharmaceutical company developing differentiated therapeutics for the treatment of neurodegenerative and neurodevelopmental disorders today reported topline results from the randomized, double-blind, placebo-controlled,

Phase 2/3 EXCELLENCE clinical trial, which evaluated the clinical efficacy, safety, and tolerability of 30 mg ANAVEX®2-73 in 92 pediatric patients with Rett syndrome (RTT) between the ages of 5 through 17 years. Participants were randomized 2:1 (ANAVEX®2-73 [62 patients] to placebo [30 patients]) for 12 weeks, followed by a week 16 safety visit. As well, Anavex reported positive Real World Evidence (RWE) feedback from Rett syndrome patients under Compassionate Use Authorization.

This was the very first study of ANAVEX®2-73 in pediatric patients with Rett syndrome. After 12 weeks, the study showed improvement on the key co-primary endpoint Rett Syndrome Behaviour Questionnaire (RSBQ), which is a detailed 45-item questionnaire for assessing multiple Rett syndrome characteristics by the patients' caregivers. The other co-primary endpoint, the Clinical Global Impression – Improvement scale (CGI-I), which represents a less granular assessment by the site investigators using a seven-point scoring (one="very much improved" to seven="very much worse"), was not met.

In an ad-hoc analysis, using the predefined mixed-effect model for repeated measure (MMRM) method, after 12 weeks of treatment, ANAVEX®2-73-treated patients improved LS Mean (SE) -12.93 (2.150) points on their RSBQ total score compared to LS Mean (SE) -8.32 (2.537) points in placebo-treated patients. The LS Mean difference (SE) of -4.61 (2.439) points between treated and placebo groups did not reach statistical significance (n=77; p=0.063). ANAVEX®2-73-treated patients demonstrated a rapid onset of action with improvements at 4 weeks after treatment with a RSBQ total score LS Mean (SE) -10.32 (2.086) points in the drug-treated group compared to a LS Mean (SE) -5.67 (2.413) points in placebo-treated patients. The LS Mean difference of -4.65 (2.233) points between treated and placebo groups was statistically significant (n=77; p=0.041).

When looking at other placebo-controlled Rett syndrome trials, ANAVEX®2-73 compares favorably in terms of absolute RSBQ improvements, with the caveat that cross trials comparisons have their limitations.

The key secondary endpoint, the Anxiety, Depression, and Mood Scale (ADAMS), trended favorably. In the same analysis, scores for all RSBQ and ADAMS subscales improved over the course of the study. Collectively, the RSBQ and ADAMS demonstrated improvements in multiple areas, impacting positively in particular repetitive movements, nighttime disruptive behaviors and social avoidance.

In the EXCELLENCE study, a large placebo effect was observed which may have masked the compound's therapeutic effect. Anavex believes to have identified the probable causes.

64. Anavex's EXCELLENCE study differed from the AVATAR study in several ways. The MMRM method was not used in the AVATAR study nor was an LS Mean score reported in

AVATAR. Meanwhile, the RSBQ AUC was not reported in EXCELLENCE though it had been reported in AVATAR. Notably, unlike AVATAR, Anavex used RSBQ anchored with CGI-I in EXCELLENCE, as required.

65. The EXCELLENCE study did not meet the necessary co-primary endpoints of RSBQ and CGI-I. Anavex blamed the outcome on a "large placebo effect" but provided no data to support its claim. Instead, Anavex touted the results of an "ad hoc" analysis that omitted data from 15 participants in the study without any stated reason.

66. Anavex used its "ad hoc" analysis to conceal the weakness of the EXCELLENCE study data. Specifically, Anavex's removal of 15 participants from the analysis qualifies as a modified intent-to-treat analysis. Modified intent-to-treat analyses, or mITT, are used to minimize the negative results of an ITT analysis. An mITT analysis essentially involves engaging in a post hoc exclusion of certain patients from the entire population. By using an mITT analysis, a company cherry picks the data that support its position while excluding those that inconveniently lead to a conclusion that is inconsistent with the company's stated hypothesis; namely that the drug is effective for the indications being tested.

67. The NCBI conducted a study which presented empirical evidence that mITT trials "were strongly associated with industry funding and authors' conflict of interest." *See* MONTEDORI, A., ET AL., *Modified versus standard intention-to-treat reporting: Are there differences in methodological quality, sponsorship, and findings in randomized trials? A cross-sectional study* (Feb. 28, 2011). The study reviewed more than 350 random controlled trials (RCTs), of which 56 were mITT. The study referred to several articles which state that post-hoc exclusion of subjects in randomized trials leads to biased estimates of the treatment effect. The study goes on to state that in most cases of post hoc exclusion, it is due to the work of the pharmaceutical industry:

> In the medical literature, there is plenty of evidence that the pharmaceutical industry is directly or indirectly involved at different stages in the conduct, design and publication of biomedical research. The selection of an inappropriate comparison group (e.g., a drug with non-equivalent dosage), multiple reporting of studies and suppression or delay of publications are all circumstances where the presence of industry sponsorship are well documented.

68. The study concluded that:

> Well-designed RCTs require strict adherence to the intention-to-treat principle, in which subjects should remain in the group to which they were originally allocated. Although further research is needed to document that the mITT is a potential source of bias, to limit unjustified exclusions, the misuse of "intention-to-treat" terminology should be abandoned, and authors need to adhere to the standard intention-to-treat principle.

69. Thus, the use of mITT is used in most cases where the results lead to inconvenient truths by parties (such as Anavex) which depend on favorable results to maintain the drug's appeal in the eyes of its investors.

70. Analysts responded immediately and negatively to Anavex's announcement of the EXCELLENCE results. Adam Feuerstein of *STAT News* noted the seven-month delay in reporting the results as well as the suspicious nature of the "ad hoc" analysis. He concluded that ANAVEX 2-73 was no longer a viable candidate for Rett Syndrome treatment.

71. Other analysts also regarded the results negatively. For example, H.C. Wainwright lowered its price target for Anavex to $40 per share from $54 per share on the basis that the EXCELLENCE data would "not enable Anavex to secure regulatory approval of [ANAVEX 2-73] in Rett [S]yndrome near-term." It also noted that, "[w]hile Anavex pointed to an unexpectedly high placebo response in the trial as a potential contributor to missing statistical significance and indicated that it has identified probable causes of this, no further details have been given."

72. Anavex shares tumbled in response to the EXCELLENCE results. From a closing price of $9.31 per share on December 29, 2023, Anavex's stock price fell to $6.045 on January 2, 2024 (*i.e.*, the following trading day).

73. Following the sharp decline in Anavex's stock price, Missling attended the J.P. Morgan Annual Healthcare Conference on January 11, 2024. During the conference, Missling attempted to respond to the criticism Anavex had received in connection with the EXCELLENCE study results. Missling claimed that the study "was not fully powered. Was a Phase II/III. And it is not that we were not happy about it, but we had observed a little bit too high of a placebo effect . . . ." Missling's statements about the powering of the study contradicted the fact that the EXCELLENCE had been over-enrolled, which in turn would have increased the power of the study (*i.e.*, results are typically more reliable in larger sample sizes).

V. FALSE AND MISLEADING STATEMENTS

February 1, 2022

74. On February 1, 2022, Anavex hosted a special conference call to discuss the AVATAR trial results. Defendant Missling participated in the call on behalf of Anavex.

75. During the call, an analyst from BTIG asked Missling to confirm which endpoints Anavex would use for the EXCELLENCE trial in light of the last-minute changes to the AVATAR trial's endpoints. In pertinent part, Missling stated as follows:

> <Yun Zhong, BTIG, LLC, Research Division – Analyst>: So one question -- so follow-up question on the endpoint. And I assume that when you report top line data from the EXCELLENCE study, it will be RSBQ AUC as well? And do you have to go back to the U.S. Phase II study to reanalyze the data using AUC versus the -- as compared to the original RSBQ to make everything consistent?
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> <Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: Good question. Thank you. So that's right, ***the EXCELLENCE study will use the same endpoint*** . . . . because it's just described, ***it is just the preference of the FDA***.

(Emphasis added.)

76. The statements identified above in emphasis were false and/or materially misleading. Missling knew that RSBQ AUC would not be accepted by the FDA as a primary endpoint measure for a pivotal clinical trial. The FDA had already made clear that any clinical trial used to support an NDA for ANAVEX 2-73 needed to incorporate RSBQ and CGI-I as co-primary endpoints. The FDA confirmed this requirement in connection with DAYBUE's end-of-phase 2 meeting in October 2017 and communicated it to Anavex during its pre-IND meeting between December 2017 and February 2018, and subsequently thereafter in communications about ANAVEX 2-73 development program after receiving Fast Track designation in February 2020. Indeed, Defendants intended to rely on the EXCELLENCE study as its pivotal study for ANAVEX 2-73's NDA, which is why the study protocol for the EXCELLENCE trial on ClinicalTrials.gov identified RSBQ and CGI-I as the study's co-primary endpoints. Thus, Missling knew that the EXCELLENCE trial would ultimately not rely on RSBQ AUC for its primary endpoint, *i.e.*, the EXCELLENCE trial would not "use the same endpoint" as the AVATAR trial.

77. In addition, the above statements falsely represented that RSBQ AUC was "the preference of the FDA." It was not. The FDA required the use of RSBQ and CGI-I as co-primary endpoints for Rett Syndrome clinical trials. At best, RSBQ AUC measured a participant's response to a drug over various points in time. It did not measure the change in a participant's RSBQ score from baseline to end of treatment, which was what the FDA required. Furthermore, the FDA required a clinician evaluation, *i.e.*, CGI-I, in addition to a caretaker assessment, *i.e.*, RSBQ. Thus, there was a material difference between what Missling referred to as the FDA's "preference" and, in truth, the primary endpoints that the FDA required.

78. At other points during the call, Missling also misrepresented the ability of the AVATAR trial to support an NDA for ANAVEX 2-73. In pertinent part, Missling stated that:

> As an overview of the Rett syndrome program, we have now almost completed the entire program. We completed the U.S. Phase II study, and we just announced the completion of the Phase III AVATAR adult Rett syndrome study. And ongoing is still the EXCELLENCE study, which includes patients aged 5 to 17, which is a pediatric clinical study in Rett syndrome of the ANAVEX 2-73 Rett syndrome program.
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> I also like to mention that we received the Fast Track designation, Orphan Drug Designation as well as orphan drug in rare pediatric disease designation. So with that, ***we now have 1 pivotal study Phase III in adult Rett syndrome***; 1 Phase II study, which could be a supportive efficacy study in Rett syndrome; and we have extensive database and tolerability data of ANAVEX 2-73 from various other trials as well, which completes the safety package.
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> So let me give you some background, however, about the endpoints, the primary endpoint, which is very important. It has been demonstrated that statistically significance, and that is required for a successful Phase III study, is not alone sufficient for proving a drug. It's also required that the outcome of the effect of the patient is clinically meaningful for the individual patient, and that can be measurable assessed.
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> And for that reason, to pick the right endpoint is very important. As we know now, and we knew when we started the trial, the RSBQ is not the most suited stand-alone caregiver endpoint or outcome assessment for Rett syndrome. It had been shown and recently published that it could lead to either type 1 or type 2 error. The FDA hence recommended, and it's also provided in the guidelines from the FDA, and recommended specifically in these cases, because you don't have many choices endpoints to pick from which have been validated for rare diseases like Rett syndrome, to use instead the RSBQ with an anchor.
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> That's called anchor-based responder method, which links the score from 1 clinical outcome assessment, the RSBQ in this case, with scores from a simple reference anchor, which is the outcome assessment with a clinically meaningful threshold, which is the CGI-I, and that facilitates the interpretation of what constitutes a meaningful within and between patient change in clinical outcome assessment. ***And so this RSBQ AUC was born***.
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> . . .

<Charles Cliff Duncan, Cantor Fitzgerald & Co., Research Division – Senior Analyst>: Okay. And then relative to -- or regarding the endpoint, I guess I'm really intrigued with the anchor-based endpoint analysis. And I like it in some ways, but I also kind of wonder if -- I mean, didn't the trial start off with an RSBQ total? And isn't that the endpoint in the ongoing EXCELLENCE trial? And I guess I'm wondering if you also looked at the data with regard to a change in RSBQ relative to baseline.

And then the other thing I wanted to ask, which I'm confused on, is it looks like the CGI data is exactly the same as the primary endpoint data. And I'm wondering if I'm just confused in seeing that.

<Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: Yes, good point. So let me also address the second part. So the CGI-I response is indeed numerically similar or the same as the RSBQ AUC response. But that's coincidental, it's not the same in its patient response. The RSBQ total score is actually -- and we had included that in our analysis, and we basically did not change the -- or the 0 didn't change on time in the clinicaltrial.gov. That's why it looks like it was changed, but it was actually prespecified. In a Phase III, you cannot really move around with the endpoint. So it was prespecified. As I mentioned, we also included that in the RS-001, and we also showed it in our slides, but we didn't highlight that analysis. ***But the discussion with FDA led to a conviction that the RSBQ alone is not sufficient as a stand-alone to measure because of its likely type 1 and type 2 error potential. So the anchor-based correlated threshold-based RSBQ was then chosen, which is the RSBQ AUC***.

. . .

<Charles Cliff Duncan, Cantor Fitzgerald & Co., Research Division – Senior Analyst>: Okay. Last question. Sorry, for all of them, but I promise, it's the last. Next steps regarding meeting with the agency, I assume you don't know the exact timing, but could you give us kind of a goal on that?

And then would you be discussing a second Phase III to replicate these results? Or would you rely on excellence and the body of data that you have thus far to potentially support the filing of an NDA?

<Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: Yes. so I mean, it's not unheard of. We've seen it with the approval of the vaccines for COVID that it was first tested in adults, and it was then approved for adult, and then it was tested in young children, and then it was approved in our children and now the age group was expanded further. ***So we don't exclude the ability now with this data package to seek approval for Rett syndrome for adult patients***. On the other hand, we'd like to have the discussion with FDA first because we also have the, as you know, EXCELLENCE study ongoing, which includes patient 5 to 17. So regarding timing, I would like to say, at this point in

> time, as soon as we can. So we'd like to move forward the discussion as soon as possible.

(Emphasis added.)

79. The statements identified above in emphasis were false and/or materially misleading. Missling created the false impression that the AVATAR study, which used RSBQ AUC as its primary endpoint, could serve as a "pivotal" study for ANAVEX 2-73's NDA. In clinical development, the term "pivotal" signifies that the trial can support an NDA because it is designed to produced potentially acceptable evidence of a clinical benefit. RSBQ AUC had not been approved by the FDA for use as a primary endpoint in a pivotal clinical trial for Rett Syndrome. Instead, the FDA required RSBQ anchored with CGI-I. Further, although Missling claimed RSBQ AUC was the equivalent of RSBQ anchored with CGI-I, RSBQ AUC incorporated treatment responses over the course of the trial. By incorporating treatment responses of the course of the trial, participant scores did not accurately reflect improvement over baseline at end of treatment but instead essentially measured changes during the trial, which the FDA would not accept as a primary endpoint measure for use in a pivotal Rett Syndrome clinical trial. Consequently, Missling created the false impression that the FDA approved the RSBQ AUC endpoint for use in a pivotal trial and could support an NDA for ANAVEX 2-73, which was not true.

February 9, 2022

80. On February 9, 2022, Anavex hosted a conference call to discuss its quarterly results for the first quarter of fiscal 2022. Defendant Missling participated in the call on behalf of Anavex.

81. During the call, an analyst from Cantor Fitzgerald pressed Missling for clarity on the endpoints Anavex intended to use in the EXCELLENCE trial. Instead of answering the

question directly, Missling concealed the information being requested. In pertinent part, Missling stated as follows:

> <Charles Cliff Duncan, Cantor Fitzgerald & Co., Research Division – Research Analyst>: . . . Let me turn to EXCELLENCE. I guess I'm wondering if you'll use the same evaluation as was used in AVATAR because I think clin trials [ClinicalTrials.gov] has it a little bit different, and you might correct that. And then the second thing about EXCELLENCE is that in terms of the patient enrollment to date, can you give us some color on the number of patients enrolled? And when during the second half of '22 you would anticipate that study to read out?
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> . . .
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> <Christopher U. Missling Anavex Life Sciences Corp. – President, CEO, Secretary & Director>: . . . Yes. And in regards to the ClinicalTrials.gov, I would like to make, again, a statement here that the ClinicalTrials.gov is not what we want to refer as to company communication. It will be updated eventually. So I'd like to -- you to be aware of that. So the company communication is -- has priority over ClinicalTrials.gov, but ***it will be updated when we have finalized the study outcome***. And then we will also update the ClinicalTrials.gov. Right now, it might not be completely up to date. So I want to make sure people understand that.

(Emphasis added.)

82. The statements identified above in emphasis were false and/or materially misleading. Missling told investors just one week earlier during the February 1, 2022 special call that EXCELLENCE would use the same RSBQ AUC endpoint that Anavex used in AVATAR. However, Anavex's study protocol on ClinicalTrials.gov showed RSBQ and CGI-I as the co-primary endpoints for the EXCELLENCE study, which was what the FDA required. When asked for clarification by the Cantor Fitzgerald analyst, Missling refused to answer the question because, if he did, he would have been forced to admit that ClinicalTrials.gov did in fact display the correct FDA-approved endpoints and, by extension, admit that RSBQ AUC had not been approved by the FDA. Consequently, by evading the question posed directly to him Missling perpetuated the false impression that RSBQ AUC was an approved endpoint and that the AVATAR trial results would support an NDA for ANAVEX 2-73 as a Rett Syndrome treatment.

83. Later in the call, a different analyst asked Missling another question about Anavex's use of RSBQ AUC and, in particular, its appropriateness in light of Acadia Pharmaceuticals' use of the RSBQ and CGI-I co-primary endpoints. Missling again misrepresented and concealed the fact that RSBQ AUC was not approved by the FDA. In pertinent part, Missling stated as follows:

> <Soumit Roy, JonesTrading Institutional Services, LLC, Research Division – Director & Healthcare Analyst>: Congrats on this quarter and the data. One question, Chris, I wanted to understand or get your take on, how do you think FDA would look at 2 drugs being filed so close to each other with 2 different endpoints? Curious if you would make any comment if you think they would ask Acadia [Acadia Pharmaceuticals] to file it RSBQ AUC?
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> <Christopher U. Missling, Anavex Life Sciences Corp. – President, CEO, Secretary & Director>: It's an excellent question. I would like to speak just on our data. We really think that, as I mentioned before, every drug needs to be looked at in its uniqueness, and you want to analyze it with the drug effect in mind. And that's what we've done.
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> And on top of it came the paper on the RSBQ, which really has extremely high variability and baseline inconsistency. And again, I'm not speaking here out of line. It's really in this paper from 2020, which came around the time when we finished our first study in the U.S. study. And that's what we learned from that to adjust to this.
>
> ***And then the guidelines of the FDA guidance are really specific, what to do in those cases. If you have a baseline -- if you have an endpoint, which has not a totally reliability feature, then you can use what is called the anchoring and use the response analysis***.
>
> But that requires -- it's very important, and we probably should highlight it stronger that this endpoint in question needs to be correlating with the CGI. And if it doesn't correlate, you cannot use this anchoring method. So -- and you are then left with a poor outcome.
>
> But since we tested the correlation, and it should correlate because the difference between the 2 measures are the RSBQ is assessed by the parents, and the CGI are assessed by the physician. And while they measure different things, they both should basically see a positive change independently of each other. And so that means they should eventually correlate to a certain extent. And they do in our studies, and they did in those studies, which is a good thing.
>
> And so once you have established a correlation, ***then the FDA guidelines really explicitly say, please use this anchor-based method because you just also take***

> ***care of what the FDA is always concerned about not clinically -- not statistical significance, but clinically meaningfulness. And by doing this, we basically raised the bar for us, for the drug***. But we also did it to make it easier to appreciate the drug effect because now you can be assured that everybody who's a responder also has to have an improvement, which is clinically meaningful.
>
> ***So we made it for the FDA easier. That's why I think the guidance is very clear because they want to make sure that you just don't have an average statistical improvement of a certain percentage and/or score, but it doesn't mean anything to anybody***. Nobody can confirm that it is beneficial. The physician cannot assess it or confirm it. The patient cannot confirm it, and the parents cannot confirm it, but it's statistically significant. So it doesn't help anybody.
>
> So by ***using this approach of the CGI anchored RSBQ***, you'll see we were able to raise the bar, make it easy to interpret. So it's the analogy of what we just also mentioned on the 1st of February of the story of the way skin diseases are assessed in rash or other features that you have to raise -- reduce a certain amount, a minimum amount. For example, in rash, it's at 75% or even 90% before being considered even that the drug works. And this bar is what we have here included. And that allows for just more fair and proper assessment of the drug -- of the effect of the drug.

(Emphasis added.)

84. The statements identified above in emphasis were false and/or materially misleading. The FDA's guidance for Rett Syndrome clinical trials at this point was to use co-primary endpoints of RSBQ and CGI-I. The analyst made reference to Acadia Pharmaceuticals because it had just completed the LAVENDER trial for DAYBUE and reported data pursuant to these endpoints, *i.e.*, RSBQ and CGI-I. Despite Missling admitting to being aware of the guidance and even describing it as "very clear," Anavex did not adhere to it during the AVATAR trial. The RSBQ AUC endpoint used by Anavex was, in fact, closer to the "average statistical improvement" that Missling regarded as not "mean[ing] anything to anybody." Thus, Missling misled investors and analysts when claiming that the RSBQ AUC endpoint was the endpoint required by the FDA's guidance.

May 10, 2022

85. On May 10, 2022, Anavex hosted a conference call to discuss its second quarter results for fiscal 2022. Defendant Missling participated on the call on behalf of Anavex.

86. During the call, an analyst asked Missling once again if Anavex was going to use the same RSBQ AUC endpoint in its ongoing EXCELLENCE study. Missling initially avoided the question but, when asked again directly in follow-up, he responded that RSBQ AUC was the correct endpoint and would in fact be used in the EXCELLENCE study. In pertinent part, Missling stated as follows:

> <Yun Zhong BTIG, LLC, Research Division – Analyst>: On the pediatric Rett syndrome study, and I see that the study has not completed patient enrollment. So I assume it's still ongoing. So I wanted to confirm if you're going to put out the press release on patient enrollment completion? And on the primary endpoint, is it reasonable to assume that it's still going to be the AUC? And have you talked to the FDA the -- I believe the last guidance or last -- yes, business guidance after the second readout from the Rett syndrome was that you were going to talk to the FDA, so has that happened yet, please?
>
> <Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: Thank you for the call. Indeed, so the last communication is that we are planning to meet the FDA to discuss the Rett program and its procedure to move forward with filing an NDA for approval. And since we finished and completed the AVATAR study in adults, a small study despite the fact that it's a successful study, a Phase II study, which was also small and the ongoing EXCELLENCE study, which is in pediatric study, which is the largest study.
>
> So we are waiting for this meeting to take place. It has not yet taken place, but it will take place soon and then we will learn how to move forward. And indeed, direct EXCELLENCE study with pediatric patients is still ongoing enrolling, and we might have a press release when the enrollment is completed.
>
> <Yun Zhong BTIG, LLC, Research Division – Analyst>: So well, with regard to the primary endpoint, is it still going to be RSBQ AUC instead of RSBQ?
>
> <Christopher U. Missling Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: That's right. So when we have presented AVATAR study, we learned from the first Phase II study that the RSBQ AUC that includes the CGI-I linked respond analysis. ***So the RSBQ AUC includes the CGI-I respond analysis -- linked***

> ***respond analysis, that is the endpoint which we will also propose for the EXCELLENCE study. That is correct. It's consistent with the AVATAR study.***

(Emphasis added.)

87. The statements identified above in emphasis were false and/or materially misleading. As previously alleged, RSBQ AUC was not equivalent to the FDA-approved primary endpoints of RSBQ and CGI-I. Missling was aware of the FDA's guidance on this point, as evidenced by both his admitted familiarity with the "very clear" regulations, the protocol for the EXCELLENCE study on ClinicalTrials.gov, and Acadia Pharmaceuticals' LAVENDER study results. Notwithstanding, Missling falsely claimed that RSBQ AUC adhered to the regulations and would be used in the EXCELLENCE study, thereby giving analysts and investors the materially misleading impression that the FDA had approved Anavex's use of the RSBQ AUC measure as an endpoint for the EXCELLENCE trial.

November 28, 2022

88. On November 28, 2022, Anavex hosted a conference call to discuss its fourth quarter results for fiscal 2022. Defendant Missling participated on the call on behalf of Anavex.

89. During the call, an analyst once again asked Missling if the EXCELLENCE trial would rely on the RSBQ AUC endpoint that Anavex had previously used in the AVATAR trial. Missling again refused to disavow the RSBQ AUC endpoint and/or otherwise admit that the FDA required the co-primary endpoints of RSBQ and CGI-I. In pertinent part, Missling stated as follows:

> <Charles Cliff Duncan, Cantor Fitzgerald & Co., Research Division – Senior Analyst>: Okay. And then moving on to the EXCELLENCE study. In terms of the endpoint, can you help us understand what is the endpoint that you're most focused on? Is it RSBQ AUC in Rett? Or is it the Clinical Global Impression of Improvement?

> <Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: It's really both. So the RSBQ is the assessment of the parents and the CGI-I is the assessment by the physician. So both are relevant and they should actually match or correlate with each other. And so we believe ***both endpoints are critical***.

(Emphasis added.)

90. The statements identified above in emphasis were false and/or materially misleading. Despite knowing that RSBQ AUC had not been approved by the FDA and would not be accepted in support of a pivotal Rett Syndrome clinical trial, Missling continued to falsely represent that it would be used in the EXCELLENCE trial. This gave investors and analysts the materially misleading impression that the FDA had authorized Anavex to use the RSBQ AUC measure as a primary endpoint, which was not the case. In fact, as of August 2022, Anavex had submitted the "existing design" of the EXCELLENCE study to the FDA "in order to make sure that the agency [was] comfortable with [Anavex's] design," according to Missling. That design, as reflected on ClinicalTrials.gov, showed the use of the FDA-approved co-primary endpoints of RSBQ and CGI-I and not RSBQ AUC.

January 12, 2023

91. On January 12, 2023, Anavex participated in the 41st Annual J.P. Morgan Healthcare Conference. Defendant Missling presented on behalf of Anavex.

92. During the presentation, Missling continued to obscure the truth about Anavex's reliance on RSBQ AUC and mislead investors into believing that its endpoint in the AVATAR trial was, in fact, the ones that had been used by Acadia Pharmaceuticals and approved by the FDA. In pertinent part, Missling stated as follows:

> <Unknown Analyst>: Okay. Next question. On Rett syndrome so Acadia has noticed diarrhea in your clinical study. Has Anavex seen any similar adverse effect in clinical studies?

<Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: Yes, that's a very good question. So diarrhea was not noticed in our clinical studies. And what's important maybe to be aware of in Rett syndrome, these girls usually have constipation. So the opposite of diarrhea. So it's really also important to have adverse event profile, which is less invasive and disturbing overall in these patients. So no, we have not noticed this diarrhea adverse events in our clinical studies.

<Unknown Analyst>: Got it. Okay. We have a couple of others? Questions? Another one on Rett syndrome. What are the limitations of the RSBQ as an endpoint?

<Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: So in Rett syndrome, there are not many clinical outcomes developed because it's a rare disease and there have not been many clinical trials so far. The RSBQ is a patient administered endpoint or outcome. That's why it's also important to be aware of that who makes the assessment, if it's the parent.

And what was reported in a publication recently was that the RSBQ seems to have a very high variability in repeat measures between time points without any intervention. So that makes it a little bit of like an imprecise baseline measure and outcome measure.

And we -- for that reason, we used in our analysis of our trial, an anchor-based methodology by using the CGI-I, a measure of more concrete assessment by an independent group of assessors, which are the physicians. So that allows for a more objective assessment, and we anchored the CGI-I to the RSBQ outcome, and that allows for reducing variability of this RSBQ. But again, you cannot replace the RSBQ because there are not many alternatives which are in Rett syndrome as validated endpoints. But that's a very good way of also raising the bar of using respond analysis, using a threshold of net improvement and not just having an outcome number of change from baseline, which is more a rigorous approach in respond analysis with a threshold of net improvement with -- which the CGI-I anchored RSBQ is. ***So we basically are able to address the perfection of the RSBQ as a stand-alone by this methodology***.

(Emphasis added.)

93. The statements identified above in emphasis were false and/or materially misleading. As previously alleged, RSBQ AUC was not equivalent to the FDA-approved primary endpoints of RSBQ and CGI-I. Missling was aware of the FDA's guidance on this point, as evidenced by both his admitted familiarity with the "very clear" regulations, the protocol for the

EXCELLENCE study on ClinicalTrials.gov, and Acadia Pharmaceuticals' LAVENDER study results. Notwithstanding, Missling falsely claimed that Anavex's use of RSBQ AUC in the AVATAR trial adhered to the regulations and was equivalent to the RSBQ and CGI-I co-primary endpoints approved by the FDA.

February 2, 2023

94. On February 2, 2023, Anavex issued a press release titled "Anavex Life Sciences Announces Exceeding of Enrollment Target for ANAVEX®2-73 (blarcamesine)." The press release contained an obscure reference to Anavex's communications with the FDA and its receipt of input relating to the endpoints for the EXCELLENCE study. In pertinent part, the press release stated as follows:

> Anavex Life Sciences Corp. ("Anavex" or the "Company") (Nasdaq: AVXL), a clinical-stage biopharmaceutical company developing differentiated therapeutics for the treatment of neurodegenerative and neurodevelopmental disorders including Alzheimer's disease, Parkinson's disease, Rett syndrome and other central nervous system (CNS) diseases, today announced the total enrollment of 92 patients with Rett syndrome for the ANAVEX®2-73 (blarcamesine) EXCELLENCE Phase 2/3 study in Rett syndrome patients ages ≥ 5 years to 17 (inclusive). This exceeds the original enrollment target and the Company expects to announce topline results from this study in 2H 2023.
>
> ANAVEX®2-73 is an orally available, small-molecule activator of the sigma-1 receptor (SIGMAR1) which, data suggest, is pivotal to restoring neural cell homeostasis and promoting neuroplasticity.
>
> The enrollment completion of the randomized, placebo-controlled EXCELLENCE Phase 2/3 study ANAVEX®2-73-RS-003 for the treatment of pediatric patients with Rett syndrome was preceded by the successful completion of both placebo-controlled Phase 2 U.S. (ANAVEX®2-73-RS-001), and Phase 3 AVATAR (ANAVEX®2-73-RS-002) studies in adult patients with Rett syndrome.
>
> The multi-center, double-blind clinical EXCELLENCE study (ANAVEX®2-73-RS-003) in pediatric patients is measuring safety, tolerability, and efficacy of daily oral ANAVEX®2-73 doses or placebo. After completing the double-blind study, eligible participants are able to join a voluntary open-label extension study of ANAVEX®2-73. ***In communication with the FDA, we received their input on the endpoints, which were utilized in this study***.

> ANAVEX®2-73 (blarcamesine) had previously received Fast Track designation, Rare Pediatric Disease designation and Orphan Drug designation from the FDA for the treatment of Rett syndrome.

(Emphasis added.)

95. The statements identified above in emphasis were materially misleading. Prior to this point, Missling had repeatedly told analysts and investors that RSBQ AUC was the endpoint being used in the EXCELLENCE trial and created the false impression that the FDA had approved it. This was not true though. In reality, the FDA had approved only the use of RSBQ and CGI-I as co-primary endpoints in Rett Syndrome trials. Thus, when Anavex referenced "communication with the FDA" in the above press release, that communication consisted of the FDA telling Anavex that it could not use RSBQ AUC but instead needed to use RSBQ and CGI-I as co-primary endpoints if it wanted the EXCELLENCE trial to serve as a pivotal trial for ANAVEX 2-73's NDA. Instead of disclosing this to investors, the above press release perpetuated the false impression that Anavex's use of RSBQ AUC in both the AVATAR and EXCELLENCE trials were in line with FDA guidance, which was not the case.

February 7, 2023

96. On February 7, 2023, Anavex hosted a conference call to discuss its first quarter results for fiscal 2023. Defendant Missling participated on the call on behalf of Anavex.

97. During the call, an analyst questioned Missling about the endpoints in the EXCELLENCE trial and, in particular, his communications with the FDA referenced in the press release dated February 2, 2023. In pertinent part, Missling stated as follows:

> <Yun Zhong, BTIG, LLC, Research Division – Analyst>: Okay. And then switching to the Rett syndrome study. I believe though your press release announcing over enrollment had the language that with the FDA's input, you are using the primary end point. So I wanted to confirm that the primary end point is RSBQ AUC similar to -- or the same to the one used in the AVATAR study? And -- so has the FDA

agreed that AUC, the modified RSBQ scale, can be an appropriate end point for Rett syndrome study?

<Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: ***Yes. We have it described in clinicaltrial.gov, and it was also never changed in clinicaltrial.gov for the EXCELLENCE study. It is the RSBQ as primary end point, and the CGI-I is key secondary end point over the course of the trial***.

<Yun Zhong BTIG, LLC, Research Division – Analyst>: Is that the same end point that was used in the AVATAR study?

<Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: Slightly different. So it's actually the measurement over time from beginning to end of trial.

<Yun Zhong, BTIG, LLC, Research Division – Analyst>: Not AUC?

<Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: Not AUC.

<Yun Zhong, BTIG, LLC, Research Division – Analyst>: Not AUC?

<Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: Exactly, yes.

<Yun Zhong, BTIG, LLC, Research Division – Analyst>: Okay.

<Christopher U. Missling, Anavex Life Sciences Corp. – Chairman, President, CEO & Secretary>: ***Because the study is large enough that it can carry the signal by itself without AUC***.

(Emphasis added.)

98. The statements identified above in emphasis were materially misleading. Despite the material differences between RSBQ AUC on the one hand and RSBQ anchored with CGI-I on the other hand, Missling represented that they were equivalent and implied falsely that they had both been approved by the FDA. Indeed, the BTIG analyst asked point-blank whether RSBQ AUC had been approved by the FDA as an "appropriate end point" for the EXCELLENCE study and, in response, Missling said "yes". Missling then referred the analyst to the EXCELLENCE study's

posting on ClinicalTrials.gov, which listed the correct co-primary endpoints of RSBQ with CGI-I, thereby implying falsely that the measures were equivalent to one another and, by extension, the RSBQ AUC measure used in the AVATAR trial would still acceptable and meritorious in support of a regulatory approval package for ANAVEX 2-73, *i.e.*, an NDA.

99. Notwithstanding Missling's initial response, the analyst continued to press for a direct answer on whether EXCELLENCE would use RSBQ AUC as its primary endpoint. Missling eventually conceded it would not while at the same time maintaining the false impression that RSBQ AUC would still be an acceptable measure for the AVATAR trial. In truth, RSBQ AUC was not an acceptable endpoint for a pivotal Rett Syndrome clinical trial. Furthermore, although Missling claimed that RSBQ AUC would not be used in the EXCELLENCE trial because "the study [was] large enough that it can carry the signal by itself without AUC," in truth it was the FDA's requirements that forced Anavex to reveal it would not be using the RSBQ AUC measurement and not the size of the trial. In fact, as Defendants would ultimately disclose, the size of the trial was too small causing it to be underpowered.

August 8, 2023

100. On August 8, 2023, Anavex hosted a conference call to discuss its third quarter results for fiscal 2023. Defendant Missling participated on the call on behalf of Anavex.

101. During the call, Missling discussed the clinical data he and Anavex had received from its various ANAVEX 2-73 trials, which included the U.S.-based Phase 2 trial as well as AVATAR. He also discussed the data from the EXCELLENCE study that had completed over two months earlier on June 6, 2023. Despite having the totality of the data in hand at this point and knowing that it was insufficient in light of the FDA's decision to grant approval to DAYBUE in March 2023, Missling misrepresented the strength of the data by once again providing a

description of the results using measurements that were not approved by the FDA. In pertinent part, Missling stated as follows:

> <Christopher U. Missling, Anavex Life Sciences Corp. – President, CEO, Secretary & Director>: Thank you, Clint, and good morning, everyone. Thank you for being with us today to review our most recently reported financial results and to provide our quarterly business update.
>
> We are very excited to be entering an important phase of the company with several key data readouts within the remainder of 2023 for blarcamesine.
>
> First on Rett syndrome. In June, we announced the completion of the placebo-controlled EXCELLENCE Phase II/III clinical trial, RS-003, in pediatric patients with Rett syndrome and we're looking forward to the top line data of this potentially pivotal clinical trial in the second half of 2023.
>
> On June 12, we announced the publication of a new peer-reviewed study in the American Journal on Intellectual and Developmental Disabilities with relevance to this clinical trial entitled, Rett Syndrome Behavior Questionnaire in Children and Adults with Rett Syndrome: Psychometric Characterization and Revised Factor Structure.
>
> In the EXCELLENCE clinical trial, they have characterized Rett Syndrome Behavior Questionnaire, RSBQ, together with the Clinical Global Impression Improvement Scale, CGI-I, represents the co-primary efficacy endpoints of the trial. This psychometric study is timely and significant as it provides additional support for the use of the RSBQ in children and adults as well as reference values and revised subscales for its improved use.
>
> We have also been further encouraged for the results of this upcoming data readout based on recent long-term clinical trial results from the U.S. ANAVEX-2-73-RS-001 clinical trial, which we announced end of June. The long-term data demonstrated disease-modifying effect of blarcamesine for adult patients with Rett syndrome.
>
> ***Results from pharmacometric modeling of the full clinical data from baseline of the double-blind study to the end of the open-label extension study indicated that the data are best characterized with a combined symptomatic and disease-modifying drug effect model, meaning that blarcamesine exhibited both symptomatic and disease-modifying effects in the treatment of Rett syndrome in a clinical setting.***
>
> ***Continued improvement from the drug as measured with the RBSQ total score was observed from the start of the double-blind study to the end of the open-label extension for patients continuing on blarcamesine.***

> Additionally, disease progression, which is defined as the change in Rett syndrome disease severity with time was also reduced with long-term treatment with blarcamesine.

(Emphasis added.)

102. The statements identified above in emphasis were materially misleading. By the time of the third quarter earnings conference call: the FDA had already granted approval to Acadia Pharmaceuticals' DAYBUE based on its pivotal LAVENDER trial; Missling had openly acknowledged that the correct co-primary endpoints for EXCELLENCE were RSBQ and CGI-I, and not RSBQ AUC; and the EXCELLENCE trial had been completed for over two months with the data unblinded and in-hand. Thus, Missling knew that Anavex's collective trial data from the U.S.-based Phase 2 trial, the AVATAR trial, and the EXCELLENCE trial was insufficient to support a regulatory approval package. Indeed, the AVATAR trial incorrectly used RSBQ AUC as its primary endpoint and the EXCELLENCE trial had failed to meet the correct co-primary endpoint measures, *i.e.*, RSBQ and CGI-I. Instead of admitting this reality, Missling resorted to portraying ANAVEX 2-73's trial data through the lens of a "responder" analysis, *i.e.*, RSBQ AUC. By characterizing the data using a "combined symptomatic and disease-modifying drug effect model" and measuring responses "from the start . . . to the end," Missling was able to falsely cast the clinical trial results for ANAVEX 2-73 in a materially positive light.

103. By concealing the weakness of ANAVEX 2-73's clinical data, Missling was able to maintain a false sense of hope and expectation around Anavex's Rett Syndrome commercial opportunities. Indeed, following the third quarter conference call on August 8, 2023, analysts reported positively on the EXCELLENCE study and maintained their ratings and price targets on the stock. For example, Jones Research wrote that Anavex's Rett Syndrome program "remains an upside to the current implied valuation" based on its "expect[ation] to get registration enabling

topline data from the [EXCELLENCE] trial." Likewise, H.C. Wainwright wrote that it "continue[d] to expect that Anavex could submit [ANAVEX 2-73] to the FDA in Rett [S]yndrome before the end of 2023, assuming favorable data from the EXCELLENCE trial, with possible approval and U.S. market entry in mid- to late 2024 assuming Priority Review."

VI. ADDITIONAL SCIENTER ALLEGATIONS

104. Defendants acted with scienter at all relevant times. Missling's scienter is imputed to Anavex under the doctrine of *respondeat superior* and/or common law principles of agency because at all relevant times Missling was acting within his scope of employment as Anavex's CEO, President, and Secretary.

105. In addition to the facts previously alleged, Missling's scienter is evidenced by his familiarity with Anavex's clinical trial operations and, in particular, ANAVEX 2-73's clinical trials for Rett Syndrome. Missling's familiarity with these trials is demonstrated by his frequent discussion of the U.S.-based Phase 2 trial, AVATAR, and EXCELLENCE trials throughout the Class Period. Further, despite Anavex having had a Chief Scientific Officer (Dr. Walter E. Kaufmann) and a Chief Medical Officer (Dr. Edward Hammond) throughout the Class Period, Missling discussed the trials and the trial data on behalf of Anavex during its investor presentations and earnings conference calls. This was true even when, for example, Missling was accompanied by Dr. Hammond on the February 1, 2022 special conference call to discuss the AVATAR trial results. Missling's nearly exclusive role in discussing ANAVEX 2-73's clinical data demonstrates that he was intimately familiar with the trials, perhaps more than anyone else at Anavex.

106. Missling's familiarity with the trials and trial data is also evidenced by the fact that Anavex had <40 employees throughout the relevant period. According to analysts, ANAVEX 2-73 for Rett Syndrome represented the most likely and nearest opportunity for commercialization and

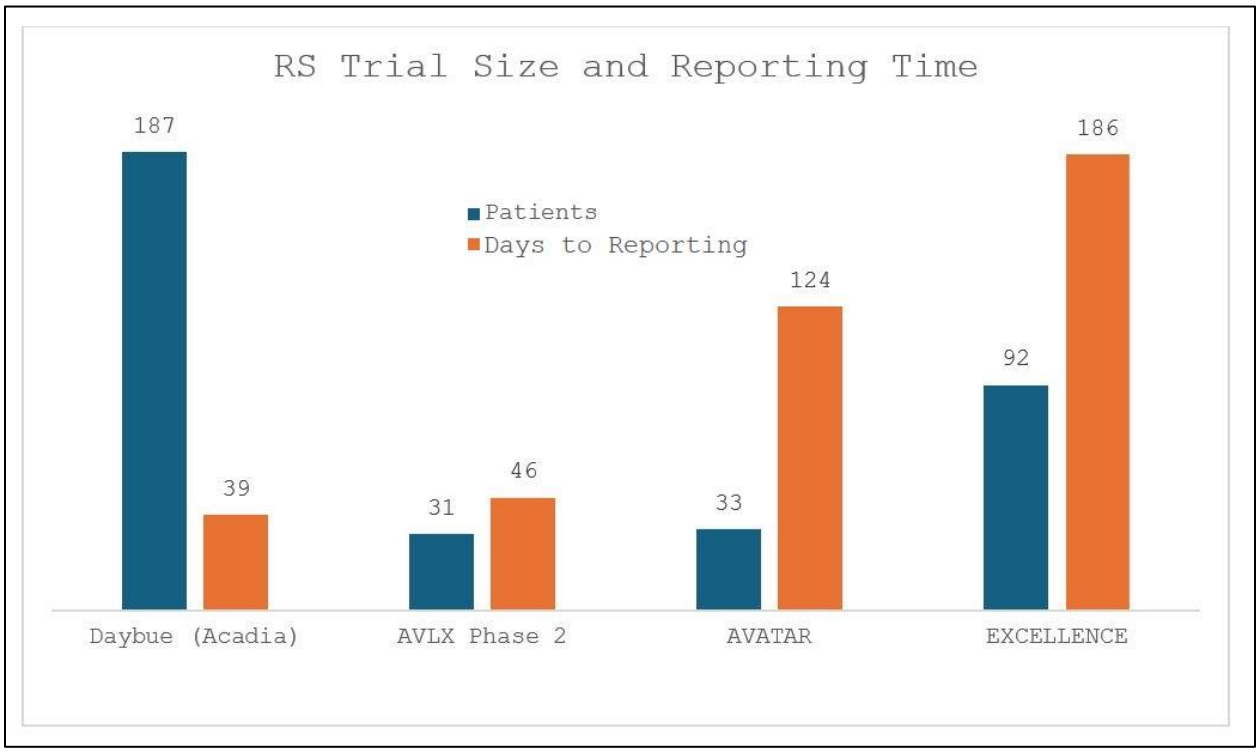
revenue. Consequently, the importance of the trials combined with Anavex's relatively small size all but guarantees that Missling was involved with the trials on a day-to-day basis and oversaw their progress directly.

107. Scienter is further evidenced by Missling's consistent attempts to evade analyst questioning about ANAVEX 2-73's clinical trial program and data. Given the knowledge he possessed about the trials, his attempted refusals to answer certain questions illustrates an intention on his part to conceal certain material adverse information. For example, on February 9, 2022, Missling avoided answering analyst questions directly on the topic of which endpoints Anavex intended to use in the EXCELLENCE trial. Similarly, on May 10, 2022, he again tried to sidestep an analyst question directly seeking confirmation concerning the endpoints for the EXCELLENCE trial.

108. Missling's desire to conceal material adverse information relates in part to the fact that Anavex had no revenue generating commercial products. Consequently, its primary source of capital was the share purchase agreements it had with Lincoln Capital whereby Anavex was allowed to sell shares to Lincoln Capital at market price; Lincoln Capital was then allowed to turn around and resell them to retail investors in the open market. If materially adverse information entered the public sphere, Anavex's stock price would decrease. *See* Loss Causation, *infra* (discussing disclosures on February 7, 2023 and January 2, 2024). Pursuant to these share purchase agreements, Anavex sold $24.1 million of stock to Lincoln Capital in fiscal 2021 and another $27.9 million in fiscal 2023. Anavex's ability to raise this money would have been jeopardized had Missling not prevented adverse information from reaching public investors. This, in turn, would have jeopardized Missling's lucrative compensation packages.

109. Throughout the Class Period, Defendants exhibited a pattern of delaying the announcement of bad news. Specifically, Anavex completed the AVATAR trial on September 30, 2021 yet did not report results until February 1, 2022, *i.e.*, 124 days later. Similarly, Anavex completed the EXCELLENCE trial on June 30, 2023 but delayed reporting results until January 2, 2024, *i.e.*, 186 days later. Pursuant to industry standards and customary practices, topline data from clinical trials is typically reported within six to eight weeks of study completion.

110. The following chart illustrates the significance of Anavex's delayed reporting tactics. It compares the amount of time between study completion and reporting across Acadia Pharmaceuticals' LAVENDER trial and Anavex's U.S.-based Phase 2 trial, AVATAR trial, and EXCELLENCE trial. Notably, the LAVENDER trial was significantly larger in terms of patient populations yet presented no difficulties with respect to reporting in line with industry practices:



111. Missling delayed reporting adverse clinical trial data from the AVATAR and EXCELLENCE trials and then, when he finally reported the data, provided it with a "spin" that

falsely portrayed it in a positive light. Examples of the "spin" include Missling's use of RSBQ AUC for the AVATAR trial as well as the mITT "ad hoc" analysis from the EXCELLENCE trial results, both of which signaled manipulation and/or misreporting of the data. Missling's conduct in this regard evidences an intent to conceal material adverse information from investors and further demonstrates his motive to commit fraud.

112. Simultaneously, Missling knew the EXCELLENCE study announcement would have a dramatic impact on the price of Anavex's stock. In an attempt to counterbalance the looming announcement, Missling caused Anavex to issue a series of bullish press releases between November and December 2023. Press releases are highly planned events by companies because they tend to have a tremendous effect on their stock price. The timing of their release dates matters and great forethought is often given to when and what time a release is issued.

113. Following the completion of the EXCELLENCE study, Missling knew that the data would be insufficient to support a regulatory approval package. Consequently, he began issuing press releases with positive headlines and attractive graphics. For example, on November 20, 2023, Missling caused Anavex to issue a press release titled, *Anavex Initiates Regulatory Submission of Oral Blarcamesine for Alzheimer's Disease to the European Medicines Agency (EMA)*; on December 19, 2023, he caused Anavex to issue a press release titled, *Anavex Received Agreement from the Committee for Medicinal Products for Human Use (CHMP) for the Submission of a Marketing Authorisation Application of Oral Blarcamesine for Alzheimer's Disease*; and on December 20, 2023, he caused Anavex to issue a press release titled, *Anavex Announces First Entire Clinical Gene Pathway Data of ANAVEX®2-73 from AVATAR Study in Patients with Rett Syndrome*, which supposedly featured a "heatmap" of patient data to support claims of a "genome" discovery. Despite these press releases having little-to-no substantive value, they created their

intended effect and inflated Anavex's stock price by nearly 100% in the short two-month window just prior to the negative EXCELLENCE study announcement.

VII. LOSS CAUSATION

114. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Anavex stock and/or maintained a pre-existing level of artificial inflation in the price of Anavex stock, and operated as a fraud or deceit on Class Period purchasers of Anavex stock by failing to disclose and misrepresenting the adverse facts detailed herein. When Defendants' prior misrepresentations and fraudulent conduct were disclosed, became apparent, and/or materialized through adverse developments, the price of Anavex stock fell precipitously. As a result of their purchases of Anavex stock during the Class Period, Plaintiff and the other investors suffered economic loss, *i.e.*, damages, under the federal securities laws when the truth about Anavex was revealed through the disclosures specified herein, which removed the false inflation from the price of Anavex common stock.

115. The clinical data for ANAVEX 2-73 was materially weaker than represented, thereby creating an elevated level of risk around obtaining regulatory approval and/or commercializing the drug as a Rett Syndrome treatment. Defendants initially misrepresented and concealed the weakness of the data (and, in turn, the risks relating to approval and commercialization) by presenting the AVATAR trial data under an RSBQ AUC endpoint analysis. On February 7, 2023, Defendants revealed to investors and analysts that they would not be using the RSBQ AUC endpoint in the EXCELLENCE trial pursuant to FDA guidance, thereby indicating that the AVATAR trial results were potentially not as positive or supportive as initially represented. This created additional uncertainty around Anavex's pathway to regulatory approval and,

consequently, sent Anavex's share price tumbling. On February 7, 2023, Anavex's stock price closed at $11.75 per share; from there it fell to $10.93 per share on February 8, 2023 and $10.41 per share on February 9, 2023 following analyst reports on the disclosure.

116. Thereafter, Defendants continued to misrepresent the strength of ANAVEX 2-73's clinical data by discussing it in the context of an RSBQ AUC analysis, which allowed Defendants to characterize the drug as having a positive "responder" effect. This created the false impression that Anavex's regulatory approval package was potentially sufficient to win approval and begin commercialization in the near-term. The truth about ANAVEX 2-73's clinical data, however, came to light when Defendants reported topline data from the EXCELLENCE trial. On January 2, 2024, six months after the trial was completed, Defendants finally revealed that the EXCELLENCE trial did not meet its co-primary endpoints of RSBQ and CGI-I. Analysts immediately reacted to the news and lowered their valuations to account for needing additional clinical trials and more time before Anavex could potentially gain FDA approval and begin generating revenue from ANAVEX 2-73 as a Rett Syndrome treatment. Anavex's stock price once again fell precipitously. From a closing price of $9.31 per share on December 31, 2023, Anavex's stock price declined to $6.045 per share on January 2, 2024, *i.e.*, the following trading day.

117. By failing to disclose to investors the adverse facts detailed herein, Defendants presented a misleading picture of Anavex's clinical trial operations and prospects for future commercialization. Anavex's false and misleading statements had the intended effect and caused Anavex stock to trade at artificially inflated levels throughout the Class Period. As a direct result of the disclosures identified herein, the price of Anavex stock fell precipitously, causing real economic loss to investors who had purchased Anavex stock at artificially inflated prices during the class period.

118. The declines on February 8 and 9, 2023 and January 2, 2024 were a direct result of the nature and extent of Defendants' fraud being revealed to investors and the market. The timing and magnitude of the price declines in Anavex stock negate any inference that the losses suffered by Plaintiff and other Class members were caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct. The economic loss, *i.e.*, damages, suffered by Plaintiff and the other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Anavex stock and the subsequent significant decline in the value of Anavex stock when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

VIII. PRESUMPTION OF RELIANCE

119. At all relevant times, the market for Anavex stock was an efficient market for the following reasons, among others:

(a) Anavex stock met the requirements for listing and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) as a regulated issuer, Anavex filed periodic public reports with the SEC;

(c) Anavex regularly communicated with public investors via established market communication mechanisms, including regular disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Anavex was followed by securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain

customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

120. As a result of the foregoing, the market for Anavex stock promptly digested current information regarding Anavex from all publicly available sources and reflected such information in the price of the stock. Under these circumstances, all purchasers of Anavex stock during the Class Period suffered similar injury through their purchase of Anavex stock at artificially inflated prices and a presumption of reliance applies under the fraud-on-the-market doctrine.

121. Alternatively, a Class-wide presumption of reliance is also appropriate in this action under the United States Supreme Court's holding in *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because the Class's claims include allegations concerning omissions. Because this action at least in part involves Defendants' failure to disclose material adverse information regarding the Company's clinical trial operations, positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of Defendants' material Class Period omissions regarding, among other things, the Company's clinical trial operations, that requirement is satisfied here.

IX. NO SAFE HARBOR

122. The "Safe Harbor" warnings accompanying Anavex's reportedly forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability. To the extent that projected revenues and earnings were included in the Company's financial reports prepared in accordance with Generally Accepted Accounting Principles, including those filed with the SEC on Form 8-K, they are excluded from the protection of the statutory Safe Harbor.

123. Defendants are also liable for any false and misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Anavex who knew that the FLS was false. In addition, the FLS were contradicted by existing, undisclosed material facts that were required to be disclosed so that the FLS would not be misleading. Finally, most of the purported Safe Harbor warnings were themselves misleading because they warned of "risks" that had already materialized or failed to provide meaningful disclosures of the relevant risks.

X. CLASS ACTION ALLEGATIONS

124. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Anavex stock on the NASDAQ during the Class Period (the "Class"). Excluded from the Class are Defendants and their families; the officers and directors of the Company, at all relevant times; members of their immediate families and their legal representatives, heirs, successors, or assigns; and any entity in which Defendants have or had a controlling interest.

125. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Anavex shares trade on the NASDAQ and has more than 82 million shares outstanding, owned by hundreds, if not thousands, of persons.

126. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to members of the Class which predominate over questions that may affect individual Class members include:

(a) whether Defendants violated the 1934 Act;

(b) whether Defendants omitted and/or misrepresented material facts;

(c) whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether Defendants knew or recklessly disregarded that their statements were false and misleading;

(e) whether the price of Anavex stock was artificially inflated; and

(f) the extent of damages sustained by Class members and the appropriate measure of damages.

127. Plaintiff's claims are typical of those of the Class because Plaintiff and the other Class members sustained damages from Defendants' wrongful conduct.

128. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

129. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

COUNT I

Defendants Violated Section 10(b) and SEC Rule 10b-5

130. Plaintiff incorporates by reference and realleges each and every allegation above as though fully set forth herein.

131. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

132. Defendants violated Section 10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) employed devices, schemes, and artifices to defraud;

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiff and other Class members in connection with their purchases of Anavex stock during the Class Period.

133. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other Class members have suffered damages in connection with their respective purchases and sales of Anavex stock during the Class Period, because, in reliance on the integrity of the market, they paid artificially inflated prices for Anavex stock and experienced loses when the artificial inflation was released from Anavex stock as a result of the revelations and stock price decline detailed herein. Plaintiff and the other Class members would not have purchased Anavex stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

134. By virtue of the foregoing, Anavex and the Individual Defendant have each violated Section 10(b) of the 1934 Act, and Rule 10b-5 promulgated thereunder.

COUNT II

Missling Violated Section 20(a) of the 1934 Act

135. Plaintiff incorporates by reference and realleges each and every allegation above as though fully set forth herein.

136. The Individual Defendant acted as controlling persons of Anavex within the meaning of Section 20(a) of the 1934 Act. By reason of his controlling positions with the Company, and their ownership of Anavex common stock, the Individual Defendant had the power and authority to cause Anavex to engage in the wrongful conduct complained of herein. Anavex controlled the Individual Defendant and all of its employees. By reason of such conduct, the Individual Defendant is liable pursuant to Section 20(a) of the 1934 Act.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Declaring that this action is a proper class action, designating Plaintiff as Lead Plaintiff, and certifying Plaintiff as a Class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as Lead Counsel;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding such equitable, injunctive, or other relief as deemed appropriate by the Court.

XII. JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: July 12, 2024

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